

Between February and April of 2018, the House Energy and Commerce Subcommittee on Health convened a series of three legislative hearings on measures to combat the opioid crisis. At the first <u>hearing</u> on February 28, lawmakers reviewed eight bills designed to improve patient safety and bolster enforcement tools. The second <u>hearing</u>, held March 21 and 22, focused on various prevention and public health solutions as outlined in the 25 legislative proposals discussed across the two-day proceeding. At the third and final <u>hearing</u>, held across April 11 and 12, the Subcommittee reviewed more than 30 bills pertaining to coverage and payment issues in federal health programs. The chart below reflects a comprehensive list of the legislation considered by the committee.

PATIENT SAFETY AND ENFORCEMENT TOOLS			
Bill	Summary	Sponsor	Status
H.R. 2851 – Stop the Importation	Modernizes scheduling guidelines to keep pace with the fast-	Rep. Katko (R-NY); 59	Introduced 6/8/2017;
and Trafficking of Synthetic	changing nature of synthetic drugs. Gives law enforcement tools to	Cosponsors	Reported by the
Analogues (SITSA) Act (Text)	get illicit synthetic drugs off the streets without compromising		Judiciary Committee
	important public health and research protections.		7/12/2017.
H.R. 5041 – Safe Disposal of	Allows hospice workers to safely dispose of unused controlled	Rep. Walberg (R-MI)	Introduced 2/15/2018
Unused Medication Act ( <u>Text</u> )	substances in patients' homes, helping to reduce the number at risk	and Rep. Dingell (D-	
	of diversion or misuse.	MI); 5 Cosponsors	
H.R, Ensuring Patient Access	Updates federal law to improve dispensing of implantable and	Rep. Costello (R-PA)	Discussion Draft
to Substance Use Disorder	injectable therapies – developed to make abuse, misuse, and	and Rep. Nolan (DMN)	
Treatments Act ( <u>Text</u> )	diversion more difficult.		
H.R, Special Registration for	Directs HHS to promulgate interim final regulations to implement an	Rep. Carter (R-GA) and	Discussion Draft
Telemedicine Clarification Act	existing law which permits the Attorney General to issue a special	Rep. Bustos (D-IL)	
( <u>Text</u> )	registration to health care providers to prescribe controlled		
	substances via telemedicine in legitimate emergency situations, such		
	as a lack of access to an in-person specialist.		
H.R, Improving Access to	Directs the Attorney General and HHS to promulgate interim final	Rep. Gregg Harper (R-	Discussion Draft
Remote Behavioral Health	regulations to allow for community mental health or addiction	MS) and Rep. Doris	
Treatment Act ( <u>Text</u> )	treatment centers to register with the DEA to engage in the practice	Matsui (D-CA)	
	of telemedicine.		
H.R, Tableting and	Gives DEA the authority to regulate the use of tableting and	Rep. Kustoff (R-TN)	Discussion Draft
Encapsulating Machine	encapsulating machines with requirements for the maintenance of		
Regulation Act of 2018 ( <u>Text</u> )	records, inspections for verifying location and stated use, and		
	security provisions. Intended to end the use of pill presses to produce		
	counterfeit drugs.		

H.R. 2063, Opioid Preventing Abuse through Continuing Education (PACE) Act ( <u>Text</u> )	Aims to improve provider understanding of pain management treatment guidelines and best practices, early detection of opioid addiction, and the treatment and management of opioid-dependent patients by requiring 12 hours of continuing medical education on the topic every three years.	Rep. Schneider (D-IL); 13 Cosponsors	Introduced 4/6/2017
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act ( <u>Text</u> )	Would support the development and dissemination of materials giving pharmacists greater understanding and ability to decline to fill controlled substances when they suspect the prescriptions are fraudulent, forged, or appear to be for abuse or diversion.	Rep. DeSaulnier (D-CA) and Rep. Carter (R-GA)	Introduced 11/7/2017
	PREVENTION AND PUBLIC HEALTH		
Bill	Summary	Sponsor	Status
H.R. 449 – Synthetic Drug Awareness Act ( <u>Text</u> )	Requires Surgeon General to report on synthetic drugs' public health impact on youth ages 12-18	Rep. Jeffries (D-NY) 42 Cosponsors	Introduced 1/11/2017
H.R. 5002 – Advancing Cutting Edge (ACE) Research Act ( <u>Text</u> )	Grants NIH flexible authority to research new, non-addictive pain medications	Rep. Dingell (D-MI) and Rep. Upton (R-MI); 2 Cosponsors	Introduced 2/13/2018
Discussion Draft of H.R, FDA Accelerated Approval and Breakthrough Therapy Status (Text)	Opens the FDA's accelerated approval program and breakthrough therapy pathway to expedite the development and review of pain and addiction therapies	N/A	Discussion Draft
Discussion Draft of H.R, FDA Opioid Sparing ( <u>Text</u> )	Required FDA to update or issue guidance addressing alternative methods for data collection on opioid sparing and inclusion of such data in produce labeling. <i>Opioid sparing is defined as the</i> <i>development of novel, non-addictive analgesics and utilization of</i> <i>currently available non-addictive analgesics that may replace,</i> <i>delay, or reduce use of opioids</i>	Rep. Comstock (R-VA)	Discussion Draft
Discussion Draft of H.R, FDA Packaging and Disposal ( <u>Text</u> )	Directs FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids. Facilitates utilization of packaging to reduce opioid overprescribing. Requires GAO to study safe disposal of unused opioids and other medications.	Rep. Hudson (R-NC)	Discussion Draft
Discussion Draft of H.R, FDA and International Mail ( <u>Text</u> )	Streamlines and enhances FDA's tools to intercept illegal products including illicit or unapproved drugs entering the U.S through International Mail Facilities	Rep. Blackburn (R-TN)	Discussion Draft
Discussion Draft of H.R, FDA Misuse/Abuse ( <u>Text</u> )	Clarifies and strengthens FDA authority to consider misuse and abuse when determining if overall benefits outweigh risks as part of the drug approval and assessment process for opioids	Rep. Green (D-TX)	Discussion Draft

Discussion Draft of H.R, FDA Long-term Efficacy ( <u>Text</u> )	Enhances FDA authority and enforcement tools to ensure timely post-marketing studies for chronically administered opioids in light of currently limited data regarding long-term efficacy of opioids, increased addictive tendencies over time, and their overall place in treating pain	Rep. McNerney (D-CA)	Discussion Draft
An Amendment in the Nature of a Substitution (AINS) to HR 4284 – Indexing Narcotics, Fentanyl, and Opioids (INFO) Act	Directs HHS to create a public and easily accessible electronic dashboard linking to all nationwide efforts to combat the opioid crisis. Creates an Interagency Substance Use Disorder Coordinating Committee	Rep. Latta (R-OH)	N/A
H.R. 5272 – Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act (Text)	Requires entities applying for federal mental health or SUD funding to submit materials demonstrating that the proposed programs or activities are evidence-based	Rep. Stivers (R-OH) and Rep. Engel (D-NY); 4 Cosponsors	Introduced 3/14/2018
H.R. 5009 – Jessie's Law ( <u>Text</u> )	Directs HHS to implement standards for display of opioid addiction in medical records.	Rep. Walberg (R-MI) 14 Cosponsors	Introduced 3/17/2017
AINS to HR 3545 – Overdose Prevention and Patient Safety Act	Would permit SUD records to be shared for the purposes of treatment, but would enhance penalties and notification requirements in the event of an unlawful disclosure, and provide discrimination prohibitions to protect people seeking and receiving SUD treatment.	Rep. Mullin (R-OK)	N/A
Discussion Draft of H.R, A Bill to Enhance and Improve State-run Prescription Drug Monitoring Programs ( <u>Text</u> )	Authorizes the CDC to carry out certain controlled substances overdose prevention and surveillance activities to improve data collection, timeliness, and accuracy for providers and dispensers in state-run prescription drug monitoring programs (PDMPs).	Rep. Griffin (R-VA) and Rep. Pallone (D-NJ)	Discussion Draft
Discussion Draft of H.R, Poison Center Network Enhancement Act ( <u>Text</u> )	Reauthorizes the national network of Poison Control Centers that serve as the primary resource for poisoning information. These centers reduce ER visits and report year over year increases in all analgesic exposures, including opioids and sedatives.	Rep. Brooks (R-IN) and Rep. Engel (D-NY)	Discussion Draft
Discussion Draft of H.R, Eliminating Opioid-Related Infectious Diseases Act ( <u>Text</u> )	Authorizes CDC to undertake an injection drug use-associated infection elimination initiative and work with states to improve education, surveillance, and treatment of infections associated with injection drug-use.	Rep. Lance (R-NJ); Rep. Kennedy (D-MA); Rep. Collins (R-NY); Rep. Eshoo (D-CA); Rep. Barton (R-TX); Rep. Matsui (D-CA)	Discussion Draft
Discussion Draft of H.R, A Bill to Improve Fentanyl Testing and Surveillance ( <u>Text</u> )	Authorizes grants to federal, state, and local agencies for the establishment or operation of public health laboratories to detect fentanyl, its analogs, and other synthetic opioids.	Rep. Kuster (D-NH)	Discussion Draft

H.R. 5261 – Treatment, Education, and Community Help (TEACH) to Combat Addiction	Authorizes HHS to designate and support Centers of Excellence and institutions of learning that champion SUD treatment and pain management education to improve how health professionals are	Rep. Johnson (R-OH) and Rep. Tonko (D-NY); 1 Cosponsor	Introduced 3/13/2018
Act ( <u>Text</u> ) Discussion Draft of H.R, Comprehensive Opioid Recovery Centers Act ( <u>Text</u> )	taught about both SUD and pain. Establishes Comprehensive Opioid Recovery Centers (CORCs) to serve as models for comprehensive treatment and recovery, utilizing the full range of FDA-approved medications and evidence-based treatments.	Rep. Guthrie (R-KY) and Rep. Green (D-TX)	Discussion Draft
H.R. 4684, Ensuring Access to Quality Sober Living Act ( <u>Text</u> )	Authorizes SAMHSA to develop, publish, and disseminate best practices for operating recovery housing that promotes a safe environment and sustained recovery from SUD.	Rep. Chu (D-CA), Rep. Walters (R-CA), Rep. Bilirakis (R-FL), and Rep. Ruiz (D-CA); 10 Cosponsors	Introduced 12/22/2017
Discussion Draft of H.R, A Bill to Support the Peer Support Specialist Workforce ( <u>Text</u> )	Enhances CARA's Building Communities of Recovery Program and authorizes HHS to award grants to peer support specialist organizations for the development and expansion of recovery services.	Rep. Lujan (D-NM) and Rep. Johnson (R-OH)	Discussion Draft
H.R. 5176 – Preventing Overdoses While in Emergency Rooms Act ( <u>Text</u> )	Provides resources for hospitals to develop protocols on discharging patients who have presented with an opioid overdose, addressing the provision of naloxone upon discharge, connection with peer-support specialists, and the referral to treatment and other services that best fit the patient's needs.	Rep. McKinley (R-WV) and Rep. Doyle (D-PA)	Introduced 3/9/2018
H.R. 5197 – Alternatives to Opioids in the Emergency Department Act (Text)	Establishes a demonstration program to test alternative pain management protocols to limit to use of opioids in hospital emergency departments.	Rep. Pascrell (D-NJ) and Rep. McKinley (R-WV); 2 cosponsors	Introduced 3/7/2018
H.R. 5140 – Tribal Addiction and Recovery Act ( <u>Text</u> )	Makes tribes, like states, eligible to be direct grantees of "State Targeted Response to the Opioid Crisis Grants" to fight the opioid epidemic in Indian Country. Tribes would receive their own \$25 million allocation.	Rep. Mullin (R-OK); 2 cosponsors	Introduced 3/1/2018
H.R. 5102 – Substance Use Disorder Workforce Loan Repayment Act ( <u>Text</u> )	Creates a program to offer student loan repayment of up to \$250,000 for a wide range of health professionals who agree to work as a SUD treatment professional in areas most in need of their services.	Rep. Clark (D-MA), Rep. Rogers (R-KY), Rep. Sarbanes (D-MD), and Rep. Guthrie (R- KY); 5 cosponsors	Introduced 2/27/2018
AINS to HR 3692 – Addiction Treatment Access Improvement Act	Expands access to MAT by allowing clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe buprenorphine and permanently authorizes non- physician providers to prescribe buprenorphine. Would also codify	Rep. Tonko (D-NY) and Rep. Lujan (D-NM)	N/A

	regulations that increased the cap on the number of patients a physician can treat with buprenorphine to 275 patients.			
COVERAGE AND PAYMENT IN MEDICAID				
Bill	Summary	Sponsor	Status	
H.R, Limited repeal of the IMD Exclusion for adult Medicaid beneficiaries with substance use disorder (Text)	Allows state Medicaid programs from FYs 2019-2023 to remove the IMD exclusion for Medicaid beneficiaries aged 21-64 with a substance use disorder. Medicaid would pay for up to 90 total days of care in an IMD during the calendar year, with an assessment required after 30 days.	N/A	Discussion Draft	
H.R, Medicaid Pharmacy Home Act ( <u>Text</u> )	Requires state Medicaid programs to have a provider and pharmacist assignment program that identifies Medicaid beneficiaries at-risk for substance use disorder and assigns them to a pharmacy home program. Set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize. Codifies an existing requirement that Medicaid managed care plans have a similar program.	N/A	Discussion Draft	
H.R, Medicaid DRUG Improvement Act ( <u>Text</u> )	Requires all state Medicaid programs to implement Drug utilization review (DUR) activities, including limitations in place for opioid refills, monitoring of concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics), monitoring antipsychotic prescribing for children, and providing at least one buprenorphine/naloxone combination drug on the Medicaid drug formulary.	N/A	Discussion Draft	
H.R, Medicaid PARTNERSHIP Act ( <u>Text</u> )	Requires the Medicaid program in each state to integrate PDMP usage into a Medicaid provider's (including pharmacists) clinical workflow. Establishes basic criteria that a PDMP must meet to be counted as a qualified PDMP. Requires states to report to CMS on PDMP performance, the number of participating providers, and statewide trends in controlled substance utilization.	N/A	Discussion Draft	
H.R, Incentives to Create Medicaid Health Homes to Treat Substance Use Disorder ( <u>Text</u> )	Extends the enhanced match from eight quarters to 12 quarters for states to provide health home wrap-around services for treatment, if they meet quality, cost, and access targets set by CMS.	N/A	Discussion Draft	
H.R, Medicaid IMD ADDITIONAL INFO Act ( <u>Text</u> )	Directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on IMDs, due no later than January 2020. The study shall report on the requirements, standards, and oversight that State Medicaid programs have for IMDs.	N/A	Discussion Draft	

H.R, Improving Medicaid	Reduces the filing window for Medicaid claims from two years to	N/A	Discussion Draft
Data Timeliness Act (Text)	one year to provide policymakers timely, complete information for		
	understanding the evolving role of the Medicaid program.		
H.R, Medicaid Graduate	Requires state Medicaid programs to report periodically to CMS data	N/A	Discussion Draft
Medical Education Transparency	and information on how GME funds are being used to train		
Act ( <u>Text</u> )	physicians in substance use disorder and specialties essential in the		
	opioid crisis (i.e., psychiatry, addiction medicine, etc).		
H.R, Protecting NAS	Requires HHS to establish a strategy to implement recommendations	N/A	Discussion Draft
Babies Act ( <u>Text</u> )	from the report, "Protecting Our Infants Act: Final Strategy," which		
	aim to enhance the treatment and care of newborns suffering from		
	Neonatal Abstinence Syndrome (NAS).		
H.R, HUMAN CAPITAL	Provides enhanced federal medical assistance percentage to use	N/A	Discussion Draft
in Medicaid Act ( <u>Text</u> )	toward the recruitment and retention of talented leaders with specific		
	expertise and capabilities for Medicaid Director and state Medicaid		
	program leadership roles.		
H.R. 3192, CHIP Mental Health	Requires all Children's Health Insurance Program (CHIP) plans to	Rep. Kennedy III (D-	Introduced 7/12/2017
Parity Act (Text)	cover treatment of mental illness and substance use disorders.	MA); 17 Cosponsors	
H.R. 4998, Health Insurance for	Currently, foster youth with Medicaid coverage before they turn 18	Rep. Bass (D-CA); 5	Introduced 2/13/2018
Former Foster Youth Act ( <u>Text</u> )	may stay in Medicaid until the age of 26, unless they move out of	Cosponsors	
	their state. The bill allows for continued coverage even if they move		
H.R, To provide for a	to another state. Creates a demonstration project for five years for up to ten states to	N/A	Discussion Draft
demonstration project to increase	receive an enhanced match for training and technical assistance and	IN/A	Discussion Drait
substance use provider capacity	other incentive activities to enroll new providers treating substance		
under the Medicaid program	use disorder in Medicaid or expand existing substance use disorder		
(Text)	provider capacity.		
H.R, Require State	Requires state Medicaid programs to report on the 11 behavioral	N/A	Discussion Draft
Medicaid Programs to Report on	health measures that are included in CMS's 2018 Core Set of Adult	IN/A	Discussion Drait
All Core Behavioral Health	Health Care Quality Measures for Medicaid.		
Measures (Text)	Theater Care Quarty Moustres for Medicard.		
H.R. 4005, Medicaid Reentry Act	Allows state Medicaid programs to receive federal matching dollars	Rep. Tonko (D-NY)	Introduced 10/10/2017
(Text)	for medical services furnished to an incarcerated individual during		
	the 30-day period preceding the individual's release.		
H.R, Medicaid coverage	Amends title XIX of the Social Security Act to provide for Medicaid	N/A	Discussion Draft
protections for pregnant and	coverage protections for pregnant and postpartum women while		
postpartum women in treatment	receiving inpatient treatment for a substance use disorder.		
(Text)			

H.R.1925, At-Risk Youth Medicaid Protection Act ( <u>Text</u> )	Prohibits state Medicaid programs from terminating a juvenile's medical assistance eligibility because the juvenile is incarcerated. A state may suspend coverage while the juvenile is an inmate, but must restore coverage upon release without requiring a new application unless the individual no longer meets the eligibility requirements for medical assistance.	Rep. Cardenas (D-CA) and Rep. Griffith (R- VA)	Introduced 4/5/2017
	COVERAGE AND PAYMENT IN MEDICARE PART		
Bill	Summary	Sponsor	Status
H.R. 3331, To incentivize adoption and use of certified electronic health record technology ( <u>Text</u> )	Amends title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.	Rep. Jenkins (R-KS); 7 Cosponsors	Introduced 7/20/2017
H.R, CMS Action Plan (Text)	Establishes an Action Plan, including studies, reports to Congress, and meetings with stakeholders, for the purpose of addressing the opioid crisis.	N/A	Discussion Draft
H.R, Use of Telehealth to Treat Opioid Use Disorder ( <u>Text</u> )	Instructs CMS to evaluate the utilization of telehealth services in treating opioid use disorder.	N/A	Discussion Draft
H.R, Alternative Payment Model for Treating Substance Use Disorder ( <u>Text</u> )	Creates a demonstration project for an Alternative Payment Model (APM) for treating substance use disorder, including the development of measures to evaluate the quality and outcomes of treatment.	N/A	Discussion Draft
H.R, Initial Pain Assessment ( <u>Text</u> )	Adds a pain assessment as part of the Welcome to Medicare initial examination, and provide intervention about nonopioid alternatives, as appropriate.	N/A	Discussion Draft
H.R, Adding Resources on Non-Opioid Alternatives to the Medicare Handbook ( <u>Text</u> )	Directs CMS to compile education resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the "Medicare and You" handbook.	N/A	Discussion Draft
H.R, Incentivizing Non- Opioid Drugs ( <u>Text</u> )	Creates a temporary pass through payment to encourage the development of non-opioid drugs for post-surgical pain management in Medicare.	N/A	Discussion Draft
H.R, Post-Surgical Injections as an Opioid Alternative ( <u>Text</u> )	Seeks to incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments.	N/A	Discussion Draft

COVERAGE AND PAYMENT IN MEDICARE PART D			
Bill	Summary	Sponsor	Status
H.R. 3528, Every Prescription Conveyed Securely Act ( <u>Text</u> )	Requires e-prescribing, with exceptions, for coverage of prescribed controlled substances under the Medicare Part D program.	Rep. Clark (D-MA) and Rep. Mullin (R-OK); 36 Cosponsors	Introduced 7/28/2017
H.R, Mandatory Lock-In ( <u>Text</u> )	Builds off of work done in the Comprehensive Addiction Recovery Act (CARA) to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at- risk beneficiaries.	N/A	Discussion Draft
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act ( <u>Text</u> )	Seeks to standardize electronic prior authorization for prescription drugs under Medicare Part D.	Rep. David Schweikert (R-AZ); 11 Cosponsors	Introduced 1/18/2018
H.R, Beneficiary Education ( <u>Text</u> )	Requires prescription drug plans under Medicare Part D to include information on the adverse effects of opioid overutilization and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain.	N/A	Discussion Draft
H.R, Evaluating Abuse Deterrent Formulations (Text)	Directs CMS to evaluate the use of abuse-deterrent opioids in Medicare plans.	N/A	Discussion Draft
H.R, Prescriber Notification ( <u>Text</u> )	Requires CMS to establish a prescriber threshold based on specialty and geographic area, which could designate a prescriber as an outlier opioid prescriber. CMS would then be responsible for notifying prescribers identified as outliers of their status.	N/A	Discussion Draft
H.R, Prescriber Education ( <u>Text</u> )	Directs CMS to work with Quality Improvement Organizations to engage in outreach with prescribers identified as clinical outliers to share best practices.	N/A	Discussion Draft
H.R, Medication Therapy Management (MTM) Expansion (Text)	Adds beneficiaries at-risk for prescription drug abuse to the list of targeted beneficiaries to be eligible for MTM under Part D.	N/A	Discussion Draft
H.R, CMS/Plan Sharing ( <u>Text</u> )	Would help to facilitate communication between MA organizations, Part D plan sponsors, and CMS relating to substantiated fraud, waste, and abuse investigations.	N/A	Discussion Draft